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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,234	01/13/2005	Satoshi Yonehara	10873.1574USWO	8752

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902-0902
MINNEAPOLIS, MN 55402

EXAMINER	
ARIANI, KADE	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,234	YONEHARA ET AL.Y	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group II, claims 7 to 14 in the reply filed on January 10, 2007 is acknowledged.

Claims 7-14 are pending in this application and were examined on their merits.

Specification

The amendment filed on January 13, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C.132 (a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: page16 2nd paragraph line 24 replacing "7.1" by "0.7" and same paragraph line 27, replacing "twice to three times" by 'twenty to thirty times".

Applicant is required to cancel the new matter in the reply to this Office Action.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of Yonehara et al. US Patent No. 6,790,665.

Claims 1-22 of Yonehara et al. recite a method of determining an amount of glycated hemoglobin in a sample by causing a redox reaction between a glycation site of the denatured hemoglobin obtained and a fructosyl amino acid oxidase, measuring

the degree to which the redox reaction has occurred to determine an amount of the glycated hemoglobin, wherein the denatured hemoglobin is treated with a protease, the hemoglobin in the sample is treated with the tetrazolium compound (nitro compound) in the presence of a sulfonic acid compound (surfactant), a method wherein the color-developing substance develops color by oxidation, as a result of a reaction between the hydrogen peroxide and the substrate, and measuring the degree of the color by measuring the absorbance at a wavelength color-developing substance.

It would have been obvious to one skilled in the art at the time the invention was made to use the claimed method disclosed by Yonehara et al. to measure an amount of glycated protein in a sample using the above mentioned redox reaction.

Claims 7-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 14 and 15 of Yonehara et al. application No. 10/517,853.

Claims 1-11, 14 and 15 are drawn to a method of measuring an analyte (glycated protein) in a sample containing hemoglobin or hemoglobin degradation product by using a redox reaction, a fructosyl amino acid oxidase acts on the analyte, a method wherein a nitro compound and a sulfonic acid compound is added to the sample, the sulfonic acid compound is sodium lauryl sulfate, the nitro compound is 2,4-dinitrophenol, a color is developed as a result of a redox reaction, and the degree of the color developed or the amount of the substrate is measured by measuring the absorbance at a wavelength for detecting the substrate.

One of the ordinary skill in the art would have been motivated to measure an amount of glycated protein in a sample, using redox reaction in the method disclosed by Yonehara et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9 and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Yonehara et al. US patent No. 6,790,665.

Claims 7-9 and 11-14 are drawn to a method of measuring a glycated protein, in which an amount of the glycated protein is determined by treating a sample containing the glycated protein with a protease so as to degrade the glycated protein, allowing a glycated portion of a glycated protein degradation product obtained by the degradation and a fructosyl amino acid oxidase to react with each other, and measuring this redox reaction, the method comprising: carrying out the protease treatment in the presence of a sulfonic acid compound, wherein the protease treatment is carried out in the presence

of the sulfonic acid compound and a nitro compound, sodium lauryl sulfate, the protease is metalloproteinase, the redox reaction is measured by determining an amount of hydrogen peroxide generated by the reaction of the glycated portion of the glycated protein degradation product and the fructosyl amino acid oxidase, wherein the amount of the hydrogen peroxide is determined by using an oxidase to reduce the generated hydrogen peroxide and oxidize a substrate that develops color by oxidation and measuring a degree of the color that the substrate has developed, wherein the degree of the color is measured by measuring an absorbance at a wavelength for detecting the substrate.

Yonehara et al. recites a method of determining an amount of glycated hemoglobin (p.2, 00016) in a sample by causing a redox reaction between a glycation site of the denatured hemoglobin obtained and a fructosyl amino acid oxidase, measuring the degree to which the redox reaction has occurred to determine an amount of the glycated hemoglobin, and calculating a ratio of the glycated hemoglobin to the total hemoglobin in the sample from the amount of the total hemoglobin and the amount of the glycated hemoglobin, wherein the denatured hemoglobin is treated with a protease (p.2, 0023), the hemoglobin in the sample is treated with a nitro compound, 2-(4-iodophenyl)-3- (2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H-tetrazolium salt (p.1, 0009), in the presence of a surfactant (p.2, 0014), sodium lauryl sulfate (SLS) method (p.2, 0003 and 0004) a method wherein the color-developing substance is a substrate that develops color by oxidation and has developed color as a result of a reaction caused by an oxidase between the hydrogen peroxide and the substrate (p.3, 0029),

and measuring the degree of the color by measuring an absorbance at a wavelength for detecting the substrate (p.3, 0026 and 0029) and further recites the protease is metalloproteinase (p.5, 0077).

Yonehara et al. therefore clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (European patent application, EP1 002874 A2, Published June 24th, 2000) in view of Oshiro et al. (Clin. Biochem. 1982, Vol. 15, No.1, p.83-88) and further in view of Ishimaru et al. (Patent No. 6,127,138 issued Oct. 3, 2000) and further in view of Johnson et al. (Blood, 1994, Vol.83, No.4, p.1117-1123).

Claims 7 and 8 are drawn to a method of measuring a glycated protein, in which an amount of the glycated protein is determined by treating a sample containing the glycated protein with a protease so as to degrade the glycated protein, allowing a glycated portion of a glycated protein degradation product obtained by the degradation

and a fructosyl amino acid oxidase to react with each other, and measuring this redox reaction, the method comprising: carrying out the protease treatment in the presence of a sulfonic acid compound, wherein the protease treatment is carried out in the presence of the sulfonic acid compound and a nitro compound,

Claims 9-11 are drawn to the method, wherein the sulfonic acid compound is sodium lauryl sulfate (SLS), the nitro compound is 2,4-dinitrophenol, and the protease is metalloproteinase.

Claims 12-14 are drawn to the method, wherein the redox reaction is measured by determining an amount of hydrogen peroxide generated by the reaction of the glycated portion of the glycated protein degradation product and the fructosyl amino acid oxidase, wherein the amount of the hydrogen peroxide is determined by using an oxidase to reduce the generated hydrogen peroxide and oxidize a substrate that develops color by oxidation and measuring a degree of the color that the substrate has developed, wherein the degree of the color is measured by measuring an absorbance at a wavelength for detecting the substrate.

Komori et al. teaches a method of measuring a glycated protein (analyte) in a sample using a redox reaction in the presence of a tetrazolium (nitro) compound (Abstract, 0001) treating the sample with a protease (protease K, subtilisin, trypsin, amino peptidase) and degrading the glycated protein by a fructosyl amino oxidase to form hydrogen peroxide and measuring the quantity of hydrogen peroxide by measuring the degree of the color (0004, 0030, 0051), with a spectrophotometer (0059) Komori et al. further discloses the presence of a surfactant (0044).

Komori et al. further teaches the presence of reducing substances such as glutathione (GSH), and treating the samples with tetrazolium (nitro) compounds to eliminate the influence of any reducing substance (0005 and 0092).

Komori et al. does not teach sodium lauryl sulfate, 2,4-dinitrophenol, and metalloproteinase. However, Oshiro et al. teaches a method for measuring an amount of hemoglobin in a sample using the surfactant sodium lauryl sulfate or SLS (see Introduction). Moreover, particular motivation would have been derived from disclosures of Ishimaru et al., which teaches a method of measuring an amount of glycated protein in a sample by treating the glycated protein with Protease N, a metalloproteinase (Abstract and Col.11, Table 2) to enhance the sensitivity of the detection (Col.5, Lines 59-63).

Therefore, It would have been obvious to one of the ordinary skill in the art at the time of the instant invention was made, to use sodium lauryl sulfate as taught by Oshiro in the method of measuring glycated hemoglobin as taught by Komori et al., because sodium lauryl sulfate is a surfactant known to be used in methods of measuring hemoglobin also has the advantage of not generating toxic waste, at the same time it would have been obvious to use metalloprotease as taught by Ishimaru et al. in the method taught by Komori et al. since by doing so one can fragment the glycated protein more specifically and enhance the sensitivity of the detection. Moreover, Johnson et al. teaches formation of 2,4-dinitrophenyl–S-glutathione to lower the glutathione levels in the erythrocytes. Thus, it would have been obvious to one of the ordinary skill in the art at the time of the invention that 2,4-dinitrophenol (a dinitrophenol derivative) can be

used in the method according to Komori et al. to eliminate any reducing agent such as glutathione which can react with hydrogen peroxide and interfere with the measurement of the amount of glycated protein. There would have been a reasonable expectation of success since it was well known in the art at the time of invention that nitro compounds (tetrazolium compound) as well as 2,4-dintrophenol are able to bind to GSH and remove it from the medium and increase the accuracy of the measurement wherein the quantity of hydrogen peroxide formed in the redox reaction corresponds to the quantity of glycated proteins in the sample.

One of ordinary skill in the art would therefore have been motivated to use sodium lauryl sulfate as the surfactant, metalloproteinase and 2,4-dinitrophenol, in the method of Komori et al. and there would have been a reasonable expectation of success in using sodium lauryl sulfate, metalloproteinase and 2,4-dinitrophenol in the method of Komori for measuring the amount of a glycated protein, since at the time the invention was made all the steps of the claimed method, were well known in the art.

Accordingly the invention taken, as a whole is *prima facie* obvious.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examther can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651